

REMARKS/ARGUMENTS

Claims 1, 2, 5 through 15, 18 through 20, 22, 23 and 25 through 51 are pending in the application

It is noted that claim 35 was not included in the Disposition of Claims. It is Applicants' understanding that this is a typographical error, as claim 35 was never canceled nor withdrawn. Therefore, the present arguments should be considered to include claim 35.

Claims 3, 4, 16, 17, 21, 24 and 35 were previously canceled.

Claims 1, 2, 5 through 13 and 25 through 31 and 44 are now canceled.

Claims 14, 15, 18 through 20, 22, 23, 32 through 34 and 36 through 43 and 45 through 51 are now left pending.

Claims 14, 15, 22, 23, 32 through 36, 42, 43 45 through 47 and 51 have been amended to include those amendments noted in the Examiner's Notice of Allowance and Examiner's Amendment dated August 26, 2005, and to correct for typographical errors.

No new subject matter has been added.

Amendment of or cancellation of claims is being done solely to expedite prosecution of the application. Original or canceled claims may be offered in this or a continuation application. No prejudice should be inferred by the cancellation of or amendment to the presently pending claims.

Rejection of Claims 1, 2, 5 8 through 10, 13, 26 through 28 and 31

Under 35 USC § 102

Claims 1, 2, 5, 8 through 10, 13, 26 through 28 and 31 are rejected under 35 USC 102(e) as being anticipated by U. S. Patent Publication No. 2005/0025756 Erin (hereinafter "Erwin").

Claims 1, 2, 5, 8 through 10, 13, 26 through 28 and 31 have been canceled, thereby obviating the basis for this rejection. These claims may be pursued in this or another continuation application. No prejudice should be inferred by the cancellation of these claims.

Rejection of Claims 6, 7, 11, 12, 14, 15, 18 through 20, 22, 23, 25, 29, 30, 32 through 34, 36 through 42 and 43 through 51 Under 35 USC § 103(a)

Claims 6, 7, 11, 12, 14, 15, 18 through 20, 22, 23, 25, 29, 30, 32 through 34, 36 through 42 and 43 through 51 stand rejected under 35 USC 103(a) as being unpatentable over U.S. Patent Publication No. 2005/0025756 Erwin (hereinafter "Erwin") further in view of Soft Gel Technologies, Inc. EP 888774 (hereinafter "Soft Gel") and U.S. Patent Publication No. 2004/0001874 Davidson et al. (hereinafter "Davidson"). Applicant respectfully traverses the rejection for at least the following reasons.

Claim 44 has been canceled, thereby obviating the basis for this portion of the pending rejection.

The present invention pertains to a soft gelatin capsule that includes coenzyme Q-10 *solubilized* (dissolved) in limonene and packaged nutraceuticals for the administration of the solubilized coenzyme Q-10. The soft gelatin capsule can further include a carrier, such as bees wax, rice bran oil, or a fish oil. The soft gelatin capsule can also further include an antioxidant.

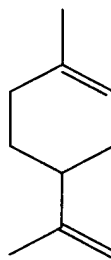
Erwin, to some degree, discloses the use of monoterpenes, such as limonene to dissolve coenzyme Q-10. The formulations Erwin discloses are liquid formulations; there is no teaching or suggestion of any delivery means other than as a free flowing liquid, such as a syrup or elixir.

Erwin fails to teach or suggest, provide any motivation or an expectation of success to one of ordinary skill in the art that a solubilized solution of limonene and coenzyme Q-10 could be encapsulated *within a soft gelatin capsule*. Absent a teaching, suggestion, or providing motivation to a skilled artisan, no reference can make obvious something which is not contemplated by the reference. As such, Erwin fails to appreciate that liquid limonene/coenzyme Q-10 could be encapsulated into a soft gelatin capsule.

Soft Gel discloses use of rice bran oil or Vitamin E to suspend coenzyme Q-10 in the carrier (rice bran oil or Vitamin E) which is formulated into a soft gelatin capsule. Soft Gel does not teach or suggest that the rice bran oil or Vitamin E solubilizes (dissolves) coenzyme Q-10.

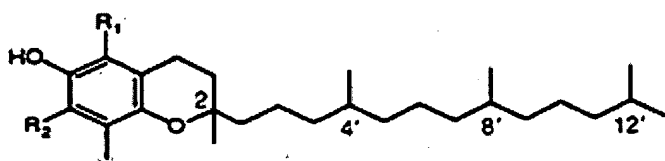
Soft Gel fails to teach or suggest, provide any motivation or an expectation of success that limonene would be a good solubilizing agent for coenzyme Q-10.

Limonene, Vitamin E and rice bran oil do not have similar chemical makeup.

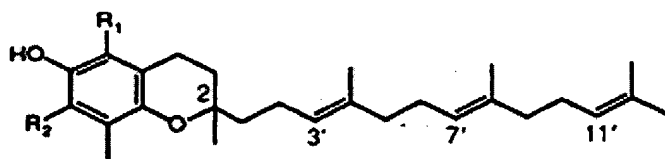


Limonene is a monocyclic terpene having the formula

Vitamin E is a mixture of four different tocopherols (α -, γ , δ , and β -tocopherols) and four corresponding tocotrienols:



R ¹	R ²	
CH ₃	CH ₃	α-Tocopherol
CH ₃	H	β-Tocopherol
H	CH ₃	γ-Tocopherol
H	H	δ-Tocopherol



R ¹	R ²	
CH ₃	CH ₃	α-Tocotrienol
CH ₃	H	β-Tocotrienol
H	CH ₃	γ-Tocotrienol
H	H	δ-Tocotrienol

The typical composition of rice bran oil is 81.3-84.3% triglycerides, 2-3% diglycerides, 5-6% monoglycerides, 2-3% free fatty acids, 0.3% waxes, 0.8% glycolipids, 1.6% phospholipids, 4% unsaponifiables. The fatty acid components of the glycerides are myristic, palmitic, stearic, oleic, linoleic, linolenic, arachidic, and behenic acids.

As should be noted, limonene has no carboxylic acid (or esters), no phenolic and no ether components as do the fatty acids of rice bran oil, and Vitamin E (respectively). Moreover, Vitamin E and rice bran oil are combinations of components, whereas limonene is a single material.

There is no teaching or suggestion, expectation of success or motivation that a skilled artisan would consider that any of the three (limonene, rice bran oil, or Vitamin E) could be interchangeable.

Soft Gel fails to remedy the deficiencies of Erwin. Soft Gel only discloses use of plant oils to formulate coenzyme Q-10. Additionally, it is not clear whether the oils solubilize the coenzyme Q-10, or merely suspend the coenzyme Q-10 in a oil phase. In contrast, limonene solubilizes the coenzyme Q-10.

Neither Erwin nor Soft Gel, alone or together, teach or suggest, provide any motivation or an expectation of success to incorporate ***solubilized*** coenzyme Q-10 in limonene into a soft gelatin capsule.

Davidson does not remedy the deficiencies of either Erwin or Soft Gel. Davidson teaches much the same as Soft Gel, in that coenzyme Q-10 can be formulated in fish oil in a soft gelatin capsule. Again, it is not known whether the fish oil solubilizes the coenzyme Q-10 or merely suspends the coenzyme Q-10.

Fish oil has as its major components, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). They are polyunsaturated fatty acids or glycerides thereof. Again, these compounds contain carboxylic acids (or esters) and do not have similar structural characteristics akin to that of limonene. Again, fish oil is a combination of at least two (2) components, whereas limonene is a single material.

There is no teaching or suggestion, expectation of success or motivation that a skilled artisan would consider that any of the two (limonene or fish oil) could be interchangeable.

None of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to incorporate ***solubilized*** coenzyme Q-10 in limonene into a soft gelatin capsule.

It is well settled that it is not proper to selectively extract individual elements from the different contexts of different references and then combine those selectively extracted elements to arrive at a claimed combination. Rather in considering the elements within the references, the references must be considered as a whole, it being impermissible to pick and choose from a reference only so much of it as will support a given position. *In re Wesslau*, 353, F.2d 238, 147 USPQ 391 (CCPA 1965); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). There is a rigorous requirement that there must be some motivation, suggestion or teaching of the desirability for selecting the elements and combining those elements in the specific combination of the invention, and the

motivation, suggestion or teaching must be disclosed in the reference(s). *In re Kotzab*, 217 F.3d 1365, 54 USPQ2d 1308, 1316 (Fed. Cir. 2000); *In re Oetiker*, 977 F.2d 14343, 24 USPQ2d 1443 (Fed. Cir. 1992). In the absence of such motivation, suggestion or teaching, it is immaterial that some, or even all, of the elements in a specific combination of an invention are known in the prior art. As clearly stated in *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453 (Fed. Cir. 1998):

As this court has stated, “virtually all [inventions] are combinations of old elements.” *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 U.S.P.Q. (BNA) 865, 870 (Fed. Cir. 1983); see also *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 U.S.P.Q. (BNA) 8, 12 (Fed. Cir. 1983) (“Most, if not all, inventions are combinations and mostly of old elements.”). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be “an illogical and inappropriate process by which to determine patentability.” *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 U.S.P.Q.2D (BNA) 1551, 1554 (Fed. Cir. 1996).

and:

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

The references cited in the September 30, 2005 Office Action do not provide a motivation, suggestion or teaching, and no showing has been made otherwise identifying in the references such a motivation, suggestion or teaching, for selecting elements from the cited

references to render obvious the method recited in independent Claims 14 and 22, and the invention cannot be used as a blueprint for identifying a suggestion or motivation. As stated in *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d (BNA) 1614 (Fed. Cir. 1999):

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2d (BNA) 1225, 1232 (Fed. Cir. 1998) (describing “teaching or suggestion or motivation [to combine]” as an “essential evidentiary component of an obviousness holding”); *In re Rouffet*, 149 F.3d 1350, 1359, 47 U.S.P.Q.2d (BNA) 1453, 1459 (Fed. Cir. 1998) (“the Board must identify specifically... the reasons one of ordinary skill in the art would have been motivated to select the references and combine them”); *In re Fritch*, 972 F.2d 1260, 1265, 23 USP.Q.2D (BNA) 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination “only by showing some objective teaching [leading to the combination]”); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d (BNA) 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion “essential” to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 U.S.P.Q. (BNA) 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it “did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination”). See also *Graham*, 383 U.S. at 18, 148 U.S.P.Q. (BNA) at 467 (“strict observance” of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 U.S.P.Q. (BNA) 543, 547 (Fed. Cir. 1985) (“The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.”). In this case the Board fell into the hindsight trap.

It has been unexpectedly found that limonene solubilizes (dissolves) coenzyme Q-10 and that solution can be encapsulated into a soft gelatin capsule. This solubilized delivery of coenzyme Q-10 is more efficacious for providing bioavailable coenzyme Q-10, thus providing an unexpected advantage over dry powdered coenzyme Q-10 acid formulations.

It is believed that all of the issues raised in this rejection have been addressed herein. Should the Examiner maintain any of the rejections of any of the pending claims, it is respectfully requested that it be pointed out with particularity how the cited reference(s) meet each and every term of each claim with respect to which rejection is maintained, and if the rejection is based on obviousness, identification of the specific motivation, suggestion or teaching in the prior art for combining elements in the specific combination off the invention.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

No fee is believed necessary. However, if payment is needed the Commissioner is hereby authorized to charge our Deposit Account No. 04-1420 and notify us of the same.

In view of the above, Applicant respectfully submits that the present application is in condition for allowance. Reconsideration of the present application and a favorable response are respectfully requested.

If a telephone conference would be helpful in resolving any remaining issues, please contact the following at 612-340-8819.

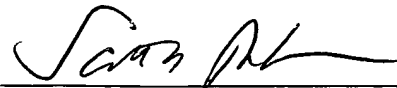
Respectfully submitted,

DORSEY & WHITNEY LLP

Customer Number 25763

Date: December 20, 2005

By:



Scott D. Rothenberger, Reg. No. 41,277
Intellectual Property Department
Suite 1500
50 South Sixth Street
Minneapolis, MN 55402-1498
Phone: 612-340-8819